

Food and Drug Administration, HHS

§ 20.100

International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

(2) Any exchange under this section of nonpublic documents does not invoke the rule established in § 20.21 that such records shall be made available to all members of the public.

(e) For purposes of this section, the term “official of a foreign government agency” includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government, or by an international organization established by law, treaty, or other governmental action and having responsibility to facilitate global or regional harmonization of standards and requirements in FDA’s areas of responsibility or to promote and coordinate public health efforts. For such officials, the statement and commitment required by paragraph (c)(1)(i) of this section shall be provided on behalf of both the organization and the individual.

[42 FR 15616, Mar. 22, 1977, as amended at 58 FR 61603, Nov. 19, 1993; 60 FR 63382, Dec. 8, 1995; 65 FR 11888, Mar. 7, 2000]

§ 20.90 Disclosure to contractors.

(a) Data and information otherwise exempt from public disclosure may be disclosed to contractors with the Food and Drug Administration and their employees for use only in their work for the Food and Drug Administration. Contractors and their employees are thereafter subject to the same legal restrictions and penalties with respect to the disclosure of such data and information as Food and Drug Administration employees.

(b) A written agreement between the Food and Drug Administration and any contractor shall be entered into before data and information otherwise exempt from public disclosure may be disclosed to the contractor. The contractor shall agree to establish and follow security precautions considered by the Food and Drug Administration to be necessary to ensure proper and confidential handling of the data and information. The

written agreement shall include, where appropriate, provisions establishing:

(1) Restrictions on access to the data and information by the contractor, its employees, or other persons;

(2) Physical storage requirements;

(3) Requirements for the handling and accountability of the data and information by the contractor and its employees;

(4) Limitations on reproduction, transmission, and disclosure of the data and information;

(5) A requirement of advance approval by the Food and Drug Administration of the use by the contractor of subcontractors, vendors, or suppliers;

(6) Procedures to be followed when the contractor employs time-shared computer operations;

(7) Methods of destroying source documents or related waste material; and

(8) The period during which the contractor may retain such data and information.

§ 20.91 Use of data or information for administrative or court enforcement action.

Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled.

Subpart F—Availability of Specific Categories of Records

§ 20.100 Applicability; cross-reference to other regulations.

(a) The provisions set forth in this subpart or cross-referenced in paragraph (c) of this section state the way in which specific categories of Food and Drug Administration records are handled upon a request for public disclosure. The exemptions established in